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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,285	02/20/2004	John D. Hatlestad	279.B40US1	7615

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,285

Applicant(s)

HATLESTAD, JOHN D.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 17-21, 24, 27-29, 31, 34, 43-46, 48, 49 and 52-56 is/are rejected.
- 7) ☒ Claim(s) 12, 14-16, 22, 23, 25, 26, 30, 32, 33, 35-42, 47, 50 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on February 20, 2004.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the bed and mattress of claims 5-9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner could find no support in the specification for specifically enabling communications between the transmission module and implantable medical device for distances greater than 10cm. It is unclear whether or not this would entail amplifiers with greater power or specialized communications equipment/circuits to enable this function.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-9, 34, 48, and 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In regard to claim 7, line 1 refers to “at least one coil”. This is indefinite since it is unclear whether this is referring to the coil of the transmission module or the coil of the implantable medical device. Claims 8 and 9 are also rejected since they depend from rejected base claim 7.

In regard to claims 34, 48, and 56, the claims are indefinite since it is unclear what is meant by the acronym “APM” (line 2 of each claim). To overcome this rejection, the Examiner recommends writing out this term.

In regard to claims 52-56, the claims are indefinite since they fail to recite any additional positive structure to the system of base claim 44. As written, they refer to method steps. To overcome this rejection, the Examiner recommends making the claim independent by re-writing the preamble of claim 52 to recite the details of claim 44 rather than referring to the claim number.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-11, 13, 17-20, 24, 27-29, 31, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al (US 2005/0043605).

In regard to claims 1, 27, and 43 the Hall et al (US 2005/0043605) U.S Patent Application Publication describes a system for communicating with an implantable medical device showing embodiments (Figs.8 and 9) reading upon applicant's claimed structure. Specifically, Fig.8 shows a patient **401** with an implantable medical device **402** lying on a support structure **405** and in communication with an external coil **454** (Fig.9) of an externally located transmission system **450**. The communication between the implantable device **402** and coil **454** is automatically established (p.4, paragraph [0052]. The use of a receiving coil in implantable device **402**, though not shown, would be inherent in order for the system of Hall et al to function properly.

In regard to claims 2, 3, 6, and 9, when patient **401** lies on support **405**, his/her body is considered to be "adjacent" to the transmission module **405**. This could conceivably occur either at night or during the daytime, since no time constraints are mentioned regarding use of the system.

In regard to claims 4-6, support structure **405** is considered to be a hard bed.

In regard to claims 7-9, applicant's attention is directed to Fig.10, which shows an embodiment where a mat/"mattress" **100** is placed on top of support structure **405**.

In regard to claims 10, the implantable medical device **402** is considered to be a cardiac rhythm management device (p.4, paragraph [0047], lines 3-4).

In regard to claim 11, device **402** may be a pacemaker (p.1, paragraph [0008], line 14).

In regard to claim 13, the pacemaker **402** includes ECG sensors (p.1, paragraph [0008], lines 1 and 12).

In regard to claims 17-20, when the patient **401** is lying flat on the structure **405**, he/she the distance between implanted device **402** and transmission module **405** is considered to be within 10cm. Especially in view of the automatic location adjustability of transmission module **405**.

In regard to claim 24, pacemaker **402** would inherently have its own power source since Hall et al does not recite the capability of external recharging.

In regard to claims 28 and 29 communications between the transmission module **450** and implanted device **402** are considered to be bi-directional since software control information is sent to device **402** (p.4, paragraph [0048]) and ECG signals are sent back to the transmission module **450** (p.1, paragraph [0008]).

In regard to claim 31, implanted device **402** is considered to be a diagnostic device since it monitors ECG information.

9. Claims 44-46, 49, 52, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Gord et al (US 5,876,425).

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In regard to claims 44-46 and 52, the Gord et al (US 5,876,425) patent describes a power control system (Figs.1 and 1A) for an implanted cochlear stimulator (ICS) 12. This system includes an external wearable system 10 including a transmitter 34, receiver 36, and antenna coil 20 for communicating with the ICS 12. The ICS 12 comprises coils for a receiver 40 and a transmitter 42, and also includes 8 rechargeable energy storage capacitors (Fig.2). The implant also includes memory in the form of a mode register 86 for storing command data. The system automatically adjusts power delivery to the ICS 12 (col.5, lines 13-17).

In regard to claims 49 and 52, applicant's attention is directed to Fig.1A, which shows data going in both directions 11,13 between the ICS 12 and wearable system 10, which performs the function of applicant's transmission module.

Allowable Subject Matter

10. Claims 21, 34, 48, and 54-56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claims 12, 14-16, 22, 23, 25, 26, 30, 32, 33, 35-42, 47, 50, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Lebel et al (US 2002/0065540) and Whitehurst et al (US 2003/0083698) patent publications are cited for their pertinent teachings of wireless communications between implantable medical devices and external devices, wherein the external devices of both may be located within mattresses. See Whitehurst et al p.8, paragraph [0093], line 2 and Lebel et al p.16, paragraph [0159], line 5.

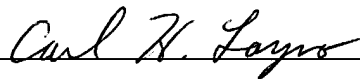
The Housworth et al (US 2004/0225337) and Abrahamson (US 2003/0014090) patent publications are also cited for their pertinent bi-directional communications circuits between implantable medical devices and external devices.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CARL LAYNO
PRIMARY EXAMINER

CHL

7/24/2006